A

Evaluation of Reprocessed Ethicon Endo-Surgery Single-Use Medical Devices

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Abstract

Ethicon Endo-Surgery, Inc. (EES) compared fourteen (14) samples of EES devices that had been refurbished, resterilized and repackaged by third party commercial reprocessors and compared them with EES product release standards. The analysis was performed using validated test methods and finished product specifications that focus on product performance criteria, in-process quality system requirements, and design requirements reflected in EES's design control system. The following results were observed.

All of the devices tested failed EES product performance requirements including labeling, traceability and component integrity. All of the devices showed evidence of residual tissue and dried blood and body fluids. In seven percent (7%) of the devices, residual tissue was lodged in places that would potentially prevent the passage of sterilization agents. Seventy-one percent (71%) of the devices failed product performance requirements. Fourteen percent (14%) of the devices contained mismatched parts. Twenty-one percent (21%) of the devices had incorrect/illegible labeling. Seven percent (7%) of the devices had an incorrect number of clips. In one hundred percent (100%) of the devices, critical information on instructions for use contained in original packaging was omitted from the new packaging of the devices.

Introduction

FDA approved disposable and reusable medical devices are sold by device manufacturers today in facilities that are required to meet FDA's Quality System Regulation guidelines. The quality of these approved devices are ensured by subjecting them through rigorous quality assurance procedures. Many of the devices at present are disposable which minimizes the risk to the patient emanating from contamination etc.

Reuse of disposable medical devices and equipment in the United States has been of interest over the past few years. Health Industry Manufacturers Association (HIMA) suggested that device reprocessors should bear responsibility for ensuring that products meet quality standards after reprocessing. Reprocessors and other industry representatives have recited that all a reprocessor does is return a device to its original condition - with no say in design or materials used. FDA has treated reprocessors much like sterilizers and contract manufacturers that work for the device manufacturers. The result is that though such firms conduct their business according to certain standards, the original device manufacturer still bears the ultimate responsibility for establishing and gaining FDA approval for marketing. At present, the completion time of FDA's review of this issue is unknown. According to Device & Diagnostics letter (March 27, 1998), two factors will be key to FDA's ultimate decision on marketing authorization requirements to reprocessed devices: (1) Whether any serious adverse events can be traced to re-use of a device and (2) how a reprocessor will be defined.

This report establishes evidence that reprocessed disposable devices contain body tissues, dried blood, and dried body fluids. These and other quality issues discovered in these devices prove that reprocessing of devices does not return them to their original condition. The tests performed at EES also provide evidence that reprocessing introduces damage which renders them not only incapable of meeting EES' acceptance criteria but also customer requirements.

Objectives

Ethicon Endo-surgery performed a rigorous Engineering analysis of 11 of its disposable medical devices that were recleaned, repackaged, and resterilized by reprocessors (ORRIS Inc., and Applied Medical). The objective of this analysis is to evaluate if these instruments meet the original device specifications, in-process validation criteria, and potential risk analysis. The investigation also included functional testing and testing for cleanliness.

Methods:

The following is the list of reprocessed Ethicon Endo-Surgery disposable devices that were evaluated for this report.

EES PRODUCT CODE	NAME	
TLC75	Linear Cutter	-
TLC55	Linear Cutter	-
TL90	Linear Stapler	-
TL30	Linear Stapler	-
TLH90	Linear Stapler	-
TIM20	Ligaclip Applier	-
BB10	Lap. Babcock	?
BA10	Lap. Ratchet Clamp	?
DCS12	Lap. Scissors	+
UV120	Veress Needle	-
CS/LCS	Harmonic Scalpel	+

A total of 14 of these instruments were evaluated to the original release criteria (Ethicon Endo-Surgery's Material Specification). Specifically, tests were performed against requirements for:

- Function
- Overall Appearance
- Product Cleanliness
- Material Strength

Results:

TLH90 / TL90

In **test report # 7433**, it is shown that excessive force was required to turn the rotation knob on reprocessed TLH90 prior to the test. This is a violation of Ethicon Endo-Surgery's functional acceptance criteria, which requires the adjusting knob on TLH90 to: (a) not be difficult to turn, (b) rotate smoothly, and (c)to hold its position. This is a minor nonconformance to customer requirements that should not affect the use or general customer acceptance of the product. However, if this nonconformance is observed on a pre-specified number of samples within a manufacturing batch, it would be deemed as not meeting EES' acceptance criteria. The handle snap on reprocessed TL90 instrument failed to engage as a result of a short cross head stroke. This would result in a EES in-process functional nonconformance.

Test report # 7484 provides confirmation for the presence of blood and/or tissue on all of the reprocessed instruments. The reprocessed TL90 Linear Stapler did not reveal any biological material when it was intact. However, when the drivers were removed, a flake of dried blood and tissue was removed from the groove in the top of one of the drivers, where it meets the staple. The TLH90 Linear Stapler showed the presence of a large flake of dried proteinaceous material in the back of the anvil assembly (photo #8). Presence of this foreign material, if toxic, will pose a safety risk to the patient. These reprocessed instruments would have failed EES acceptance criteria.

Harmonic Scalpel CS/LCS

Test report 7443

1. Functional characteristic tests on CS/LCS (**from test report 7443**) resulted in a nonconformance where the Clamp closing force value was greater than EES' acceptance criteria. This clamp force is a requirement developed to minimize the force necessary to clamp tissue and it relates to EES' ergonomic requirements.

2. The top photograph on page 6 of test report 7443 illustrates the reprocessed CS Blade. While the original Ethicon Endo-Surgery disposable blade is designed as a blunt edge blade, the reprocessed blade shown has been sharpened. Sharpening the blade is an unapproved process which can create a change in the sound wave form causing the blade to fracture and/or shatter during a cycle. This is a EES in-process functional nonconformance.

3. The photograph at the bottom of page 6 illustrates an internal component of the reprocessed device. The residue found on this component, irrespective of its composition, would have resulted in this device being classified as a nonconformance by EES. This foreign matter was not tested for toxicity.

4. The photograph at the top of page 7 illustrates an internal component of the reprocessed device. The residue found on this component, irrespective of its composition, would also have resulted in this device being classified as a nonconformance by EES. This foreign matter was not tested for toxicity.

5. The CS Clamp Pad on the reprocessed device shown at the bottom of page 7 has evidence to prove damage to the tooth profile on this device. The teeth of the clamp pad are used to grip tissue during the cut or coagulation mode. Inability to contain the tissue during a cycle can produce less than optimal results. This is classifiable within the EES' specification as a nonconformance.

6. The photographs on page 8 illustrate the CS Clamp Pad. The clamp pad was partially torn from the clamp arm. This could be the result of cleaning or additional sterilization. The clamp pad is used to grip tissue during the cut or coagulation mode. Inability to contain and apply consistent force across the tissue during a cycle can

produce less than optimal results such as the inability to complete a cut or coagulation. This too is classifiable within the EES' specification as a nonconformance.

7. In the blade assembly shown on page 9, the clamp pad was removed to view the surfaces between the clamp pad and clamp arm. The clamp arm and the clamp pad exhibit a brown substance that would result in a device nonconformance. This foreign matter was not tested for toxicity.

8. The alignment pin provided with the reprocessed device was sealed in the pouch. The plastic pin holder has rough edges and excessive flash. These edges have the potential to tear a latex glove during the surgical procedure. Should this occur, the sterile field would be violated. Since the device was not free of burrs and loose particles and was not smooth on surfaces that come in contact with the patient or operator EES would have classified this as a nonconformance.

Test report 7293

1. Functional characteristic tests on CS/LCS (**from test report 7293**) resulted in a nonconformance where the System Resonant frequency value was lower than EES' acceptance criteria. This resonant frequency is a requirement developed to optimize the performance of the system and it relates to EES' functional requirements.

2. The top photograph on page 7 of test report 7293 illustrates the reprocessed LCS Blade. While the original Ethicon Endo-Surgery disposable blade is designed to be free of any surface damage, the reprocessed blade shown has been damaged. This can cause the blade to fracture and /or shatter during a procedure cycle. This is a EES in-process functional nonconformance.

3. The photograph at the top of page 8 of test report 7293 illustrates the damaged tooth profile on the reprocessed device. The teeth of the clamp are used to grip tissue during the cut or coagulation mode. This damage to the tooth profile would have resulted in less than optimal performance and would have been classified as a nonconformance by EES.

4. The photograph on page 9 illustrates an internal component of the reprocessed device. The residue found on this component, irrespective of its composition, would also have resulted in this device being classified as a nonconformance by EES. This foreign matter, which was not tested for toxicity, would also potentially block ETO passage during resterilization.

5. The handle half on the reprocessed device shown at the bottom of page 10 has evidence to prove the presence of residue on this device. This is classifiable within the EES' specification as a nonconformance. This foreign matter was not tested for toxicity.

6. The photographs on page 11 illustrate a linkage arm residue and discoloration on the reprocessed device. The discoloration could be the result of component heating. The presence of residue is classifiable within the EES' specification as a nonconformance.

7. On the LCS shaft shown on page 12, there was residue that would result in a device nonconformance. This foreign matter was not tested for toxicity.

8. In addition, the analysis revealed that the alignment feature, a key component to assure that proper alignment is achieved, was missing from the reprocessed disposable instrument. Without proper alignment, the instrument will not function.

Linear Cutter TLC55 / 75

From the test report 7445 it is observed that three of the four TLC55 reprocessed instruments tested did not meet EES' lowest Force-to Fire acceptance requirements. As a result, the surgeon may have difficulty firing these instruments leading to incomplete staple formation, poor hemostasis etc.

The reprocessed TLC55 Linear Cutter (#4 and #11) devices shown in photo #17 (**Test report 7484**) had a different serial number for the anvil half compared to the knife half. The original EES' linear cutter is composed of two major interfacing assemblies that come together to form the handle. One of these assemblies, or handle half, contains the knife assembly. The other handle half contains the staple anvil. These devices are validated and tested as a matching set. Identical batch numbers are stamped into the handle halves to assure compatibility and traceability of component parts.

The handles on the two reprocessed devices might have been switched during the recleaning process. The presence of mismatched part serial numbers indicates that these devices are unvalidated and could lead to gross staple malformation.

Many of the devices' internal metal surfaces exhibited rust, dried blood and/or tissue especially near the anvil (photo #11). Proteinaceous material was found adjacent to the proximal end of the anvil and on some internal plastic parts (photo #4). These would have resulted in EES nonconformances.

The **Test report 7484** also illustrates a reprocessed TLC75 Linear Cutter (#2) instrument with a loose plastic plug at the distal end of the anvil that was easily removed. A great deal of proteinaceous material was found in this area (photo #16). Also, large cracks could be seen in some of the plastic parts, including the plug and parts near the knife. The presence of cracks would reduce the intended life and performance of the instrument.

Veress Needle UV120

From the results in test report # 7474, it is observed that the reprocessed device passed EES's functional acceptance criteria. However, the force to penetrate a plastic film was 0.704

lbs. compared to 0.657 lbs. for an original EES instrument. While the spring force to deflect a stylet by the reprocessed instrument was at 0.52lbs. with the window indicator fully in pink and stylet tip end extended beyond needle point, it was only 0.43 lbs. for an original EES instrument. Both the force to penetrate and spring force to deflect the stylet has shown degradation from the original EES-released instruments.

In addition, the device packaging label is not the original EES label validated for use with this device. Therefore, no device operating instructions, precautions, warnings, or contraindications are included. This is a violation of the FDA's Current Good Manufacturing Practices for Medical Devices, section 820.120b. EES would have rejected the lot / batch regardless of where the defect was found, who found it, whether or not it was found in a normal sample, or any sample size taken.

The **test results from report #7473** indicate that the UV120 Veress Needle #10 was a Pneumoneedle 120 device and included a stopcock assembly. Blood was found on the outside of the stopcock assembly, as shown in photograph. However, the UV120 Veress Needle #3 instrument was different than the #10 instrument, even though they were labeled with the same information. This is due to the polishing of the metal tube at an angle so that a section of the tubes could be peeled apart. Small flakes of dried blood were found between the tubes.

These two reprocessed disposable devices failed EES's acceptance criteria for foreign matter since they were found to contain dried blood, dried body fluids, and dried body tissue.

Laparascopic Babcock BB10

The results in the **report 7475** indicate that this device failed two of EES' functional acceptance criteria. The PVC tips (Scissors) had no PVC tips on the end effectors, and the motion of the shaft detents when rotated through 360 degrees in either direction was too stiff/erratic for proper operation. This could result in the device losing its sterility if the package is torn during shipping or handling.

This device failed EES's acceptance criteria for foreign matter. This device was found to contain dried blood, dried body fluids, and dried body tissue.

Lap. Ratchet Allis Clamp MBA 10

The results in the **report 7476** indicate that this device failed one of the EES functional acceptance criteria. The PVC tips (Scissors) had no PVC tips on the end effectors which could result in the device losing its sterility if the package was torn. The device packaging label was not the original EES label validated for use with this device. Therefore, no device operating instructions, precautions, warnings, or contraindications, are included. Based on these nonconformances EES would have rejected the batch. This device also failed EES's

acceptance criteria for foreign matter since it was found to contain dried blood, dried body fluids, and dried body tissue.

TIM20/20 Clip Applier

The following are results from test report # 7470:

I. Common Pre-fire Checks Results:

Although the device test passed the criteria for blemishes and identification, it failed the criteria for foreign matter. Small flakes of proteinaceous material were found on the cartridge, handle, and in a recessed hole, near the tip, of this device (see photo#47, and test report # 7473). These flakes tested positive for blood.

This device does not meet EES's acceptance criteria for foreign matter, since the presence of this substance materially reduce the marketability and usability of the product for it's intended use. If this substance proves to be toxic, it may cause significant injury or illness to a customer or patient. EES would reject the entire batch if one such defect is found.

II. Common Firing Checks

During firing, the reprocessed device operated satisfactorily and there were no visual seam separation. The instrument's firing mechanism fully functioned when actuated, and the clip did not stick in the tracks of the clip applier during actuation. However, the device did fail the acceptance criteria for proper clip count. The device contained only 19 clips, the acceptance criteria is 20 clips. Since the number of clips is reduced, the surgeon may not be able to complete the procedure with this instrument.

DCS12 5mm Endoscopic Curved Scissors

The following are results from test report # 7471

Although the device test passed the criteria for blemishes and identification, it failed the criteria for foreign matter. A small flake of proteinaceous material was found on the blade of the scissors (see photo# 42, and test report # 7473). This flake tested positive for blood.

This device does not meet EES's acceptance criteria for foreign matter, since the presence of this substance materially reduce the marketability and usability of the product for it's intended use. If this substance proves to be toxic, it may cause significant injury or illness to a customer or patient. EES would reject the entire batch if one such defect is found.

PN120 Pneumoneedle and Stopcock Assembly

The following are results from test report # 7472:

Although the device test passed the criteria for blemishes. It failed the criteria for identification and foreign matter.

Identification: The product label on the package of this reprocessed device, listed the product as a U120, Veress Needle. The product is actually a Pneumoneedle, product code PN120 (see photo# 38, report # 7473). This is a violation of section 820.120 of the Current Good Manufacturing Practices for Medical Devices. In addition, a small flake of proteinaceous material was found on the outside of the stopcock assembly (see photo# 39, test report #7473). This flake tested positive for blood.

This device does not meet EES's acceptance criteria for device labeling. EES considers this a major defect, that may cause significant injury or illness to a customer or patient. EES would reject the entire batch if one such defect is found.

This device does not meet EES's acceptance criteria for foreign matter, since the presence of this substance materially reduce the marketability and usability of the product for it's intended use. If this substance proves to be toxic, it may cause significant injury or illness to a customer or patient. EES would reject the entire batch if one such defect is found.

Summary of results from the test reports

Mechanical Device Testing

All mechanical devices were found to contain dried blood, dried body fluids, and dried tissue which had not been removed by the cleaning process. Foreign matter was also found in areas of the device that is not normally exposed to tissue in actual application. This implies that the foreign material could have been transferred during the recleaning process.

There were no cases where the materials failed strength testing. However, one device was received with a bent barrel. An additional device had a locked rotary knob. Root Causes for these failures could not be determined.

A majority of the mechanical devices tested passed the functional in-process acceptance criteria. However, it should be noted, that the original validation testing determined these devices to have at least 99% reliability rating with 95% confidence for a predetermined number of firings. Wear out of components due to reprocessing and reuse will affect the design life of the reused instruments. The end result could be anything from an annoyance to the customer to severe patient consequences.

If the numbers of firings exceed the validated design limit, there is an increased probability of instrument failure, including catastrophic failure. Because the probability of catastrophic failure increases after the validated design limit has been reached and the surgeon using the reprocessed device may not be aware of the number of firings a single-use instrument has been through, reprocessing can affect the successful completion of the surgical procedure.

Electromechanical Device Testing

All electromechanical disposable devices evaluated for cleanliness were found to contain dried blood, dried body fluids, and dried tissue which had not been removed by the cleaning process.

As with the mechanical instruments, this foreign matter could be easily introduced into the next patient.

In contrast to the mechanical devices, all electromechanical devices tested failed the functional test. The reprocessing of these devices introduces damage which renders the device incapable of meeting its acceptance criteria.

Other Quality Concerns

Material Integrity

Analysis indicates that there is a strong evidence that the cleaning agent used to reprocess these instruments could have damaged several of the plastic components contained in these devices. This damage to material integrity typically causes the components to degrade and become brittle.

Sterilization

Analysis revealed that internal clearances, in some of the devices tested, were clogged with dried blood and body fluids which can restrict the flow of gasses necessary to achieve effective ETO sterilization.

Conclusion

Based on the observations, there is evidence to show that reprocessed disposable devices cannot provide adequate quality to the customer or meet safety and effectiveness criteria for EES devices. The extreme amounts of foreign matter found, errors in packaging, and the functional testing results point to a high probability for instrument malfunction, misuse and patient risk. Therefore, the use of reprocessed disposable devices pose a great risk to the health and well being of the surgical patient.

References

1. "Reuse of Single-use medical devices: making informed decisions", Special Report. Plymouth Meeting (PA): ECRI: 1996

2. "Medical Device Reprocessing: Research and Practice", Biomedical Instrumentation and Technology, Volume 31, No. 3 and 4, 1997

3. Devices and Diagnostics Letter, Washington Business Information Inc., March 27, 1998.

Reliability Test Laboratory reports

Evaluation of Reprocessed Ethicon Endo-Surgery, Inc. Single-Use Medical Devices
Ethicon Endo-Surgery Inc.

Date: January 27, 1999 (submitted to FDA)

Objective: To perform a rigorous analysis of reprocessed medical devices labeled for single use, using validated test methods and finished device specifications. These devices were awaiting reuse in additional patients.

Methods: Various single-use surgical instruments were studied. These included tissue staplers, scissors, clamps, needles, clip appliers, graspers and cutters.

Reprocessed used single use devices were obtained from hospital shelves where they were awaiting reuse in patients. They were subjected to physical, microbiological and functional testing to determine whether or not they complied with original device specifications.

Results: Observations and/or product failures:

n=180 [20 each of 9 device groups]

	Product Integrity	Foreign Material	Performance
Shears/Scissors	Fail	Present	Fail
Cutters	Fail	Present	Fail
Clamps/Graspers	Fail	Present	Pass
Staplers	Fail	Present	Fail
Clip Appliers	Fail	Present	Pass
Veres needles	Fail	Present	Pass

Virtually all of the reprocessed devices examined were found to contain dried blood, body fluid, and/or tissue that had not been removed by the cleaning process. In addition, device integrity and functional performance failures were found to be causally related to the reprocessing procedures.

Conclusions: Reprocessed single use devices demonstrate compromised device integrity and altered the device safety and efficacy profiles. Using such devices on more than one patient will jeopardize patient safety.